SECTION IV

JAN 30 2009

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew Biosure PK Interference Screw

Date Prepared: December 5, 2008

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover, MA 01810

B. Company Contact

Christina Flores

Regulatory Affairs Specialist II

T 508-261-3705

F 508-261-3620

C. Device Name

Trade Name:	Biosure PK Interference Screw
Common Name:	Screw, Fixation, Bone
Classification Name: fixation fastener	21 CFR 888.3040 - Smooth or threaded metallic bone

D. Predicate Devices

The Smith & Nephew Biosure PK Interference Screw is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: Smith & Nephew BIOSURE HA Interference Screw (K080358), Smith & Nephew BioRaptor 2.3PK Suture Anchor (K071586), and Arthrex Interference Screw (K062466)

E. Description of Device

Reattachment of ligament, tendon, soft tissue, or bone to bone in, shoulder, foot/ankle, knee, elbow and hand/wrist.

F. Intended Use

The Smith & Nephew BIOSURE PK Interference Screws are indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. All screws with a diameter of 9 mm or less and a length of 25 mm or less are also intended for use in the following procedures:

Knee

- ACL Repairs
- PCL Repairs
- Extra-capsular repairs
  - Medial collateral ligament
  - Lateral collateral ligament
  - Posterior oblique ligament
- Patellar realignment and tendon repairs
  - Vastus medialis obliquous advancement
- Iliotibial band tenodesis

Shoulder

- Capsular stabilization
  - Bankart repair
  - Anterior shoulder instability
  - SLAP lesion repairs
  - Capsular shift or capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff tear repairs
- Biceps tenodesis

Foot and Ankle

- Hallux valgus repairs
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions
- Bunionectomy
- Flexor Hullucis Longus (FLH)
- Tendon Transfers

Elbow, Wrist, and Hand

- Biceps tendon reattachment
- Ulnar or radial collateral ligament reconstructions
- Lateral epicondylitis repair
- Scapholunate ligament reconstruction
- Tendon Transfers
- Carpometacarpal Joint Arthroplasty
- Carpal Ligament Reconstruction

G. Comparison of Technological Characteristics

The Smith & Nephew Biosure PK Interference Screw is substantially equivalent in intended use, technological characteristics, and is as safe and as effective as its currently marketed predicate devices, the Smith & Nephew BIOSURE HA Interference Screw (K080358), the Smith & Nephew BioRaptor 2.3PK (K071586) and the Arthrex Interference Screw (K062466)

H. Summary Performance Data

The performance testing conducted demonstrates that the insertion and fixation properties of the Smith & Nephew Biosure PK Interference Screw are substantially equivalent to the Smith & Nephew BIOSURE HA Screw, the Smith & Nephew BioRaptor 2.3PK and the Arthrex Interference Screw.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 2009

Smith & Nephew, Inc., Endoscopy Division
% Ms. Christina Flores
150 Minuteman Road
Andover, Massachusetts 01810

Re: K083635
Trade/Device Name: Biosure PK Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: December 5, 2008
Received: December 8, 2008

Dear Ms. Flores:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

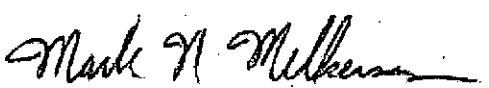
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083635

Device Name: Smith & Nephew BIOSURE PK Interference Screws

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- Carpometacarpal Joint Arthroplasty
- Carpal Ligament Reconstruction

Prescription Use ___x_____ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083635